PATENT COOPERATION TREATY

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 412912	**FOR FURTHER ACTION**	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/US 03/30577	International filing date *(day/month/year)* 26.09.2003	Priority date *(day/month/year)* 27.09.2002
International Patent Classification (IPC) or both national classification and IPC A61B5/055		
Applicant THE TRUSTEES OF DARTMOUTH COLLEGE et al.		

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.

2. This REPORT consists of a total of 6 sheets, including this cover sheet.

   ☒ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

   These annexes consist of a total of 11 sheets.

3. This report contains indications relating to the following items:

   - I ☒ Basis of the opinion
   - II ☐ Priority
   - III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
   - IV ☒ Lack of unity of invention
   - V ☒ Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
   - VI ☐ Certain documents cited
   - VII ☐ Certain defects in the international application
   - VIII ☐ Certain observations on the international application

Date of submission of the demand	Date of completion of this report
21.04.2004	01.03.2005
Name and mailing address of the international preliminary examining authority: European Patent Office - P.B. 5818 Patentlaan 2 NL-2280 HV Rijswijk - Pays Bas Tel: +31-70-340-2040 Tx: 31-651 epo nl Fax: +31 70 340 - 3016	Authorized Officer Manschot, J Telephone No. +31 70 340-4451

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/US 03/30577

I. Basis of the report

1. With regard to the **elements** of the international application *(Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17))*:

Description, Pages

2-20	as originally filed
1	received on 21.04.2004 with letter of 16.04.2004

Claims, Numbers

1-14	as originally filed

Drawings, Sheets

1/10-10/10	received on 21.04.2004 with letter of 16.04.2004

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

   These elements were available or furnished to this Authority in the following language: , which is:

   ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).

   ☐ the language of publication of the international application (under Rule 48.3(b)).

   ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

   ☐ contained in the international application in written form.

   ☐ filed together with the international application in computer readable form.

   ☐ furnished subsequently to this Authority in written form.

   ☐ furnished subsequently to this Authority in computer readable form.

   ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

   ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

   ☐ the description, pages:

   ☐ the claims, Nos.:

   ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)).

   (Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

   ☐ the entire international application,

   ☒ claims Nos. 4,5,8-14

   because:

   ☐ the said international application, or the said claims Nos. relate to the following subject matter which does not require an international preliminary examination (specify):

   ☐ the description, claims or drawings *(indicate particular elements below)* or said claims Nos. are so unclear that no meaningful opinion could be formed *(specify)*:

   ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

   ☒ no international search report has been established for the said claims Nos. 4,5,8-14

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

   ☐ the written form has not been furnished or does not comply with the Standard.

   ☐ the computer readable form has not been furnished or does not comply with the Standard.

IV. Lack of unity of invention

1. In response to the invitation to restrict or pay additional fees, the applicant has:

   ☐ restricted the claims.

   ☐ paid additional fees.

   ☐ paid additional fees under protest.

   ☒ neither restricted nor paid additional fees.

2. ☐ This Authority found that the requirement of unity of invention is not complied with and chose, according to Rule 68.1, not to invite the applicant to restrict or pay additional fees.

3. This Authority considers that the requirement of unity of invention in accordance with Rules 13.1, 13.2 and 13.3 is

   ☐ complied with.

☒ not complied with for the following reasons:

see separate sheet

4. Consequently, the following parts of the international application were the subject of international preliminary examination in establishing this report:

☐ all parts.

☒ the parts relating to claims Nos. 1-3,6,7 .

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes:	Claims	1-3,6,7
	No:	Claims	
Inventive step (IS)	Yes:	Claims	1-3,6,7
	No:	Claims	
Industrial applicability (IA)	Yes:	Claims	1-3,6,7
	No:	Claims	

2. Citations and explanations

see separate sheet

Section IV: Non-Unity

This Authority considers that there are 3 inventions covered by the claims indicated as follows:

I. Claims 1-3,6-7
Method and system for determining electromagnetic properties of an inhomogeneous target.

II. Claims 4,5:
Method of determining electrical properties of an inhomogeneous target.

III. Claims 8, 9-14
Method and system for encoding motion within biological tissue.

The reasons for which the inventions are not so linked as to form a single general inventive concept, as required by Rule 13.1 PCT, are as follows:

These three groups are not so linked as to form a single general inventive concept since there is no technical relationship which finds expression in the claims in terms of the same or corresponding special technical features (Rule 30 EPC), as explained below. In terms of features the common concept linking together the independent claims of groups 1 and 2 is that they both refer to the use of electromagnetic waves. With respect to groups 1 and 2, their common concept is that their independent claims refer to MRI. However such features are well known in the art (see the documents cited in the description of the application). The aforementioned groups are further directed to solve different technical problems, namely: - group 1 solves the problem of determining electromagnetic properties of an inhomogeneous target; - group 2 solves the problem of determining electrical properties of an inhomogeneous target in an MR environment; - group 3 solves the problem of encoding motion in a subject. Hence, the present application lacks unity within the meaning of Article 82 EPC.

Section V

The subject-matter of claims 1 and 6 (and of the claims dependent thereon) concern a method and apparatus for determining electromagnetic properties of an

inhomogeneous target based on the irradiation of the target with short pulses of EM energy (300MHz-3GHz) to induce thermoelastic waves within the target and on the detection of the mechanical displacements associated with the waves using MRI (useful in detection of breast tumour).
The prior art does not disclose the use of MRI for detecting displacement waves induced by short EM waves. US2002115924 discloses Method to assess a spatial regularity of reflecting members in a tissue. Irradiation of the tissue with EM waves and detection of the waves reflected by the tissue using MRI. One or more parameters are then calculated, based upon the reflected waves, indicative of a degree of spatial disorder of reflecting members in the tissue. No reference to the frequencies of the used waves.
The documents relating to MR- Elastography (MRE) always refer to irradiation with acoustic waves (low frequencies except in US-A-5810731).
The transmission and effects on the tissues of HF acoustic waves does not seem to be comparable to the transmission and effects of HF EM waves, so that an inventive step can be seen in this differentiating feature.
Consequently, the subject-matter of claims 1 to 3 and 6 to 7 appear to meet the requirements of Article 33 (2)-(3).

For the assessment of the present claims 1-3 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to diagnostic methods. Present claims 1 to 3 seem to relate to a diagnostic method (breast tumour detection) practised on the living human of animal body by inducing displacements within the object (breast).